510 (k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Identification: Second set of InstaCheck® Multi-Drug Screen Panels

Description: One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of THC, Cocaine, PCP, Morphine, Methamphetamine, Amphetamine, Barbiturates and Benzodiazepines in urine.

Name of Manufacturer:

Forefront Diagnostics, Inc. 23561 Ridge Route Dr. Suite D Laguna Hills, CA 92653

Intended Use: The Forefront Diagnostics InstaCheck® Multi-Drug Screen Panels are in vitro screen tests for the rapid detection of target drugs/metabolites in urine. The cut-off concentration for these tests is as follows: THC: 50ng/ml, Cocaine: 300 ng/ml, PCP: 25 ng/ml, Barbiturates: 300 ng/ml, Benzodiazepines: 300 ng/ml, Morphine: 300 and 2000 ng/ml and Methamphetamine: 1000 ng/ml. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

Technology: The InstaCheck® Multi-Drug Screen Panels, like multi-drug tests from other manufacturers such as Roche, American Biotech Inc, etc. as well as currently marketed Drug Screen Single Test "predicate" devices, qualitatively measure the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Our currently marketed InstaCheck® Drug Screen Single Test Panels are used for substantial equivalence predicate kit because other manufacturers' multi-drug tests use different drug combinations compared with our InstaCheck® Multi-Drug Screen Panels. All of these products are based on the same immunochemical principle of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of InstaCheck® Multi-Drug Screen Panels were evaluated in a blind-labeled spiked control study and in a blind-labeled clinical specimen correlation study. The results of these studies demonstrate the InstaCheck® Multi-Drug Screen Panels to be substantially equivalent to the performance characteristics of the InstaCheck® Drug Screen Single Test panels, which have received 510(k) approvals. Correlation studies, using clinical specimens, produced a >97% correlation when compared to the predicate kit and GC/MS methodology. Clinical site studies, performed at Forefront Diagnostics, Inc and three independent laboratories, were also performed. The results of this study demonstrated that the InstaCheck® Multi-Drug Screen Panels can be performed by professional and laboratory personnel to obtain a visual, qualitative, rapid detection of drugs of abuse and its metabolite with an accuracy >98%.

Conclusion: For the reasons mentioned above, it may be concluded that InstaCheck® Multi-Drug Screen Panels are substantially equivalent to the InstaCheck® Drug Screen Single Test Panels presently distributed commercially.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 2098 Gaither Road Rockville MD 20850

FEB 1 7 2000

Mr. Feng Lee Manager of Regulatory Affairs Forefront Diagnostics, Inc. 23561 Ridge Route Drive Suite D Laguna Hills, California 92653

Re: K994414

Trade Name: InstaCheck® Multi-Drug Screen Panels

Regulatory Class: II

Product Code: DKZ, LAF, DIO, DJG, LDJ, DIS, JXM, LCM

Dated: December 27, 1999 Received: December 29, 1999

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Steven Butman

Enclosure

510/k) Number (# !)	12 99 11 111		Page	of
510(k) Number (if known):	K99441			
Device Name: InstaCheck® N	Aulti-Drug Screen	Panel THC/COC, MC	R 2000/M	ET Test
Indications For Use:				
The Forefront Diagnostics Inst Test is an <i>in vitro</i> screen test carboxylic acid, Cocaine : Methamphetamine in human u	for the rapid d and its metal	etection of 11-nor-& ⁹ bolite - Renzoylec	-Tetrahyo	lrocannabinol-9-
THC 11-nor-Δ9-Tetrahydrocar	nnabinol-9-carbo	exvlic acid	50 ng/i	mi
COC Benzoylecgonine		,,	300 ng/i	
MOR Morphine			2000 ng/i	
MET Methamphetamine The test kit is used to obtain a			1000 ng/r	ml
is not intended for over the coun	rect sale to lay pe	1 50ц5.		
(Division Solder off) Division of Chineal Laboratory 510(k) Number 4	Devices 414			
(PLEASE DO NOT WRITE BELOW TI	HIS LINE-CONTINU	JE ON ANOTHER PAGE	IF NEEDE	D)
Conc	currence of CDRH, (Office of Device Evaluation	on (ODE)	
Prescription Use	OR	Over-The-Counte	· Use	

		Page of
510(k) Number (if known):	K994414	
Device Name: InstaChe	eck® Multi-Drug Screen Panel THO	C/COC/PCP/MOR 2000/MET Test
Indications For Use:		
2000/MET Test is an Tetrahydrocannabinol-9	in vitro screen test for	Screen Panel THC/COC/PCP, MOR the rapid detection of 11-nor- Δ^9 -ts metabolite - Benzoylecgonine, PCP, following concentrations:
THC 11-nor-Λ ⁹ -Tetrah	ydrocannabinol-9-carboxylic aci	d 50 ng/ml
COC Benzoylecgonine	, 0. 0 0 0 0. 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	300 ng/ml
PCP Phencyclidine		25 ng/ml
MOR Morphine		2000 ng/ml
MET Methamphetamin	ie	1000 ng/ml
(Division Sign-1/4) Division of Canada 510(k) Number	9944,4	
(PLEASE DO NOT WRITE B	BELOW THIS LINE-CONTINUE ON A	NOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of	Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)	OR O	ver-The-Counter Use

				Page	of
510(k) Number (if k	known):	K994414	<u>.</u>		
Device Name:	InstaCheck [®]	Multi-Drug Screen Pane	el THC/COC/MO	OR 2000/ME	ET/AMP Test
Indications For Use) :				-
AMP Test is an 9-carboxylic acid	<i>in vitro</i> scree d, Cocaine an	staCheck [®] Multi-Drug on test for the rapid det nd its metabolite - Benz urine at the following c	ection of 11-no: oylecgonine, M	r-Δ ⁹ -Tetrah	ydrocannabinol-
		cannabinol-9-carboxyli	e acid	50 ng/ı	ml
COC Benzoyle				300 ng/1	ml
MOR Morphine				2000 ng/i	
MET Methamp				1000 ng/ml	
AMP Ampheta	mine			1000 ng/i	ml
L of Sion	n Sign-Off) of Clinical Labo	pratory Devices			
(PLEASE DO NOT	WRITE BELO	W THIS LINE-CONTINUE (ON ANOTHER PA	GE IF NEED	ED)
		Concurrence of CDRH, Office	ce of Device Evalu	ation (ODE)	
Prescription Use _ (Per 21 CFR 801.1	09)	OR	Over-The-Cou	ınter Use	
	•		(0	Optional Form	at 1-2-96)

	12	4 G 1, 1, 1	/ i	Page of	
510(k) Number (if	known):	99441	<u> </u>		
Device Name:	InstaCheck [®] Multi-D	Orug Screen Pa	anel THC/COC/N	MOR 300/AMP/BA	AR/BZO
Indications For Us	se:				
Tetrahydrocan	Diagnostics InstaChec st is an <i>in vitro</i> nabinol-9-carboxylic phetamine, Barbiturat	screen test acid. Cocair	for the rap ne and its me	id detection of etabolite - Renz	-11-nor-Δ ⁹ Ovleccoping
THC 11-nor-A	⁹ -Tetrahydrocannabir	iol O combossi	dia a sid	5 0 / 1	
COC Benzoyle	ecgonine	ioi-9-cardoxy	iic acid	50 ng/ml	
MOR Morphin	•			300 ng/ml 300 ng/ml	
AMP Ampheta				1000 ng/ml	
BAR Barbitur				300 ng/ml	
BZO Benzodia	azepines			300 ng/ml	
(Division Sign Division of Cl 510(k) Numbe	inical Laboratory Devices				
(PLEASE DO NOT	WRITE BELOW THIS LIN	IE-CONTINUE	ON ANOTHER PA	AGE IF NEEDED)	
	Concurrence	e of CDRH, Off	ice of Device Eval	uation (ODE)	_
Prescription Use	V	OR	Over-The-Cou	ınter Use	
(Per 21 CFR 801.10	7 5)				

				Page	of
510(k) Number (if k	nown):	K994414	_		
Device Name:	InstaCheck® M Test	Multi-Drug Screen Pane	el THC/COC/MO	OR 2000/MET	'/BAR/BZO
Indications For Use	· :				
BAR/BZO Test Tetrahydrocann	is an <i>in</i> abinol-9-carbo amphetamine,	aCheck [®] Multi-Drug (vitro screen test f xylic acid, Cocaine , Barbiturates and	for the rapid and its met	l detection abolite - Be	of 11-nor-Δ ⁹ - enzoylecgonine,
THC 11-nor-Δ9	-Tetrahydroca	nnabinol-9-carboxylic	e acid	50 ng/ml	[
COC Benzoylec	•			300 ng/m	
MOR Morphine				2000 ng/m	
MET Methamp				1000 ng/ml	
BAR Barbitura	tes			300 ng/m	l
BZO Benzodiaz	epines	•		300 ng/mi	l
(Division Sig Division of 5 510(k) Numb	Laboratory 1	Devices 414			
(PLEASE DO NOT		THIS LINE-CONTINUE C))
Prescription Use (Per 21 CFR 801.10	<u>/</u>	OR	Over-The-Cou	Inter Use	1-2-96)

			Pa	age	of
510(k) Number (if k	nown):	K994414			
Device Name:	InstaCheck ⁰ Test	[®] Multi-Drug Screen Panel	THC/COC/MOF	R 300/MET/	BAR/BZO
Indications For Use	:				
BAR/BZO Test Tetrahydrocann:	is an <i>h</i> abinol-9-car amphetami	nstaCheck [®] Multi-Drug S n vitro screen test for boxylic acid, Cocaine ine, Barbiturates and B	or the rapid and its metab	detection olite – Be	of 11-nor-Δ ⁹ - nzoylecgonine,
THC 11-nor- Δ^2 COC Benzoyled MOR Morphine MET Methamp BAR Barbitura BZO Benzodiaz	gonine hetamine tes	ocannabinol-9-carboxylic	acid	50 ng/m 300 ng/m 300 ng/m 1000 ng/m 300 ng/m 300 ng/m	
		a visual, qualitative resu counter sale to lay persons		ed for profe	essional use. It
(Division of Clinic Division of Clinic 510(k) Number_		Devices			
(PLEASE DO NOT	WRITE BELC	OW THIS LINE-CONTINUE OF	N ANOTHER PAG	E IF NEEDEL	D)
		Concurrence of CDRH, Office	of Device Evaluat	ion (ODE)	
Prescription Use (Per 21 CFR 801.10	09)	OR	Over-The-Count	er Usetional Format	- 1-2-96)

			ţ	Page	of	
510(k) Number (if kı	nown):	K994414				
Device Name:	InstaCheck [®] AMP Test	Multi-Drug Screen Pane	THC/COC/PC	P/MOR 20	00/MET	<i></i>
Indications For Use	:					
MET, AMP To	est is an abinol-9-carl	staCheck [®] Multi-Drug S in vitro screen test boxylic acid, Cocaine an ine and Amphetamin	for the rapid 1d its metaboli	l detectio te - Benzo	on of l oylecgon	1-nor-Δ'- ine, PCP,
THC 11-nor-A ⁹	-Tetrahydro	cannabinol-9-carboxylic	acid	50 ng	/ml	
COC Benzoyled				300 ng		
PCP Phencycli	_			25 ng	/ml	
MOR Morphine				2000 ng		
MET Methamp				1000 ng	•	
AMP Ampheta	mine			1000 ng	/ml	
Divates and C 510(k) Numb	·	ry Devices 4414				
(PLEASE DO NOT		OW THIS LINE-CONTINUE CONCURRENCE OF CORRENCE OF CORRE				
Prescription Use _ (Per 21 CFR 801.1	<u>/</u>	OR	Over-The-Cou	·		96)

	1 2 2	2/12/11/		Page	Of
510(k) Number (if k	nown): $\frac{\cancel{\cancel{K}}}{\cancel{\cancel{5}}}$	94414	_		
Device Name:	InstaCheck [®] Multi-Dr BAR/BZO Test	ug Screen Pan	el THC/COC/P	CP/MOR 30	0/AMP/
Indications For Use	:				
300/AMP, BAR/ Tetrahydrocann	Diagnostics InstaChe BZO Test is an <i>in</i> abinol-9-carboxylic ac hetamine, Barbiturate	<i>vitro</i> screen (cid, Cocaine a	est for the r nd its metabo	apid detecti olite - Benzo	on of 11-nor- Δ^9 - ylecgonine, PCP,
THC 11-nor-Δ ⁹	-Tetrahydrocannabin	ol-9-carboxyli	c acid	50 ng	/ml
COC Benzoyled	0	•		300 ng	
PCP Phencycli				25 ng	
MOR Morphine				300 ng	
/AMP Amphetai BAR Barbitura				1000 ng 300 ng	
BZO Benzodiaz				300 ng	
is not intended to	or over the counter sal	e to lay persoi	15.		
	sion Sign-Off) sion of Clinical Laboratory O(k) Number	Devices			
(PLEASE DO NOT	WRITE BELOW THIS LIN	NE-CONTINUE (ON ANOTHER F	PAGE IF NEED	DED)
	Concurrence	e of CDRH, Offic	ce of Device Eva	lluation (ODE)	
/	/				
Prescription Use (Per 21 CFR 801.10)9)	OR	Over-The-Co	ounter Use	

			Page Of	
510(k) Number (if ki	nown):	K994414		
Device Name:	InstaCheck® BAR/BZO 1	Multi-Drug Screen Panel THC	/COC/PCP/MOR 2000/MF	ET/
Indications For Use:	:			
2000/MET, BAR Tetrahydrocanna	VBZO Test abinol-9-carb 1amphetamir	InstaCheck [®] Multi-Drug So is an <i>in vitro</i> screen test fo poxylic acid, Cocaine and its ie, Barbiturates and Benzo	r the rapid detection of metabolite - Benzoylecge	11-nor- Δ^9 - onine, PCP,
THC 11-nor-A9	-Tetrahydro	cannabinol-9-carboxylic acid	50 ng/ml	
COC Benzoylec	_	cumulation y cumbony ne usia	300 ng/ml	
PCP Phencyclic	~		25 ng/ml	
MOR Morphine			2000 ng/ml	
MET Methamp	hetamine		1000 ng/ml	
BAR Barbitura			300 ng/ml	
BZO Benzodiaz	zepines		300 ng/ml	
is not intended for (Division of Division	or over the co	a visual, qualitative result an punter sale to lay persons. Paratory Devices	a is intended for professi	onai use. It
(PLEASE DO NOT		W THIS LINE-CONTINUE ON ANG	·	
Prescription Use(Per 21 CFR 801.10	/ 09)	OR Ove	er-The-Counter Use	

					Page	Of	_
510(k)	Number (if k	nown):	K994414				
Device	Name:		neck [®] Multi-Drug Screen Pa ZO Test	nel THC/COC/Po	CP/MOR 300	0/ ME T/	
Indicati	ons For Use						
300/M Tetral Morpl	ET/BAR/E hydrocanna	SZO Te abinol-9- amphet	stics InstaCheck [®] Multi- st is an <i>in vitro</i> screen -carboxylic acid, Cocaine tamine, Barbiturates and	test for the ra and its metabol	pid detection lite - Benzo	on of 11-n ylecgonine	ior-Δ ⁹ - , PCP,
			ydrocannabinol-9-carboxy	lic acid	50 ng/		
	Benzoylec Phencyclic				300 ng/ 25 ng/		
	Morphine				25 ng/ 300 ng/		
	Methamp		e		1000 ng/		
	Barbitura		-		300 ng/		
BZO	Benzodiaz	epines			300 ng/		
(PLEAS	SE DO NOT	WRITE B	ELOW THIS LINE-CONTINUE	ON ANOTHER PA	AGE IF NEED	PED)	
,		-	Concurrence of CDRH, Of	fice of Device Eval	uation (ODE)		
Prescrip (Per 21	ption Use CFR 801.10	() (9)	OR	Over-The-Co	unter Use		
		-,		((Optional Form	nat 1-2-96)	48